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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,725

06/20/2005

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT

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1652

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,725	Applicant(s) RESKI ET AL.	
	Examiner GANAPATHIRAMA RAGHU	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-40,42,48,50,78 and 81-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-40,42,48,50,78 and 81-95 is/are rejected.
- 7) ☒ Claim(s) 88-95 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Application Status

In response to the Non-Final Office Action dated 04/22/08, applicants' filed a response received on 10/21/08 is acknowledged. In said response, applicants' have amended claims 38, 40, 42, 48, 50 and 78, cancelled claims 41, 43-47, 49, 51-77, 79 and 80 and added new claims 81-95. Thus claims 38-40, 42, 48, 50, 78 and 81-95 are pending and are under consideration in the instant Office Action.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Withdrawn- Claim Rejections: 35 USC § 112

Previous rejection of claims 38-40, 42, 48, 50 and 78 rejected under 35 U.S.C. 112, second paragraph, is being withdrawn due to amendments to claims.

Previous rejection of claim 40 rejected under 35 U.S.C. 112, second paragraph, is being withdrawn due to amendments to the claim and persuasive arguments by the applicants.

Previous rejection of claim 50 rejected under 35 U.S.C. 112, second paragraph, is being withdrawn due to amendments to the claim.

Claim Objections

New claim 88 and claims 89-95 depending therefrom are objected to because of the following informality:

Applicants are advised that should claim 38 and claims 39, 40, 42, 48, 50 and 78 depending therefrom are found allowable, new claim 88 and claims 89-95 depending therefrom will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, as claim 88 is identical in scope to claim 38. When two claims in an application

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are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Maintained-Claim Rejections: 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 38-40, 42, 48, 50, 78 and 81-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a specific bryophyte *Physcomitrella patens* wherein in said *Physcomitrella patens* the endogenous gene encoding for alpha 1, 3-fucosyltransferase (FucT, 1711 bp, GenBank: partial cDNA: AJ429145, page 32 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 48, 49, 50 and 51 or an endogenous gene encoding for beta 1,2 xylosyltransferase (XylT, 1788 bp, GenBank: corresponding to the coding region: AJ429144, page 38 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 67, 68, 69 and 70 (page 39 of specification) or a double knockout comprising said FucT and XylT disrupted through targeted insertion (double knockout, disrupting the coding regions of said genes, pages 44-45 of specification), further in said single knockout or double knockout *Physcomitrella patens* the gene encoding the human beta-1,4-galactosyltransferase catalyzing the following glycosylation pattern; UDP-galactose + N-acetyl-D-glucosaminylglycopeptide \rightleftharpoons UDP + beta-D-galactosyl 1, 4,-N-acetyl-beta-D-glucosaminylglycopeptide (GalT, GenBank X55415) has been integrated by homologous recombination and said *Physcomitrella*

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patens comprising said gene knockout (FucT and XylT or double knockout) expressing the human galT is transformed with an expression construct encoding the secretable/soluble form of human vascular endothelial growth factor (VEGF), does not reasonably provide enablement for a transformed bryophyte from *Pyscomitrella patens* comprising disruption of any endogenous fucosyl transferase and xylosyl transferase of undefined structure, said bryophyte cell further comprising human beta-1,4-galactosyltransferase capable of producing human glycosylation pattern. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 38-40, 42, 48, 50, 78 and 81-95, broadly encompass: a transformed bryophyte from *Pyscomitrella patens* comprising disruption of any endogenous fucosyl transferase and xylosyl transferase of undefined structure, said bryophyte cell further comprising human beta-1,4-galactosyltransferase capable of producing human glycosylation pattern. The scope of the claims is not commensurate with the

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enablement provided by the disclosure with regard to a transformed bryophyte from *Physcomitrella patens* comprising extremely large number of FucT or XylT polynucleotides and encoding polypeptides of undefined structure as broadly encompassed by the claims as said *Physcomitrella patens* can potentially comprise multiple distinct genes comprising distinct structures and encoding polypeptides with distinct structures having FucT or XylT activities.

In this case the disclosure is limited to a specific bryophyte *Physcomitrella patens* wherein in said *Physcomitrella patens* the endogenous gene encoding for alpha 1, 3-fucosyltransferase (FucT, 1711 bp, GenBank: partial cDNA: AJ429145, page 32 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 48, 49, 50 and 51 or an endogenous gene encoding for beta 1,2 xylosyltransferase (XylT, 1788 bp, GenBank: corresponding to the coding region: AJ429144, page 38 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 67, 68, 69 and 70 (page 39 of specification) or a double knockout comprising said FucT and XylT disrupted through targeted insertion (double knockout, disrupting the coding regions of said genes, pages 44-45 of specification), further in said single knockout or double knockout *Physcomitrella patens* the gene encoding the human beta-1,4-galactosyltransferase catalyzing the following glycosylation pattern; UDP-galactose + N-acetyl-D-glucosaminylglycopeptide \Leftrightarrow UDP + beta-D-galactosyl 1, 4,-N-acetyl-beta-D-glucosaminylglycopeptide (GalT, GenBank X55415) has been integrated by homologous recombination and said *Physcomitrella patens* comprising said gene knockout (FucT and XylT or double knockout) expressing the human galT is

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transformed with an expression construct encoding the secretable/soluble form of human vascular endothelial growth factor (VEGF). This guidance provided is insufficient, as the breadth and scope of the bryophyte cell *Physcomitrella patens* comprising modifications to a genus of structurally undefined genes (diverse structures for genes associated with fucosyl transferase and xylosyl transferase functions) that are disrupted. Even the applicants in the specification on page 6, lines 10-15 have admitted that N-glycosylation is very complex and well regulated as N-glycosylation depends not only on developmental stages for plants but also dependent upon culture conditions. Therefore a skilled artisan requires the information regarding the gene structure, organization and its regulatory elements of all endogenous genes encoding the polypeptides involved in N-glycan synthesis and amenable for disruption without affecting the viability of the modified/transformed plants and the methods for transformation including specific structures such as specific primer sequences for disrupting any FucT or XylT. In addition, any given galactosyltransferase activity (said bryophytes expressing a galactosyltransferase for the production of heterologous glycosylated polypeptides) is specific and limited to certain specific substrate(s) and its spectrum of activity is also limited and specific. In view of the breadth of the claims, the amount of experimentation required, the lack of guidance, working examples, and unpredictability of the art in predicting which of the many bryophytes are amenable for said transformations, practicing the claimed invention would require undue experimentation. As such, the specification fails to enable the entire scope of the claimed invention.

The specification does not support the broad scope of the claims because the specification does not establish: **(A)** diverse structures for genes associated with fucosyl transferase (FucT) and xylosyl transferase functions (XylT) in bryophyte cell *Physcomitrella patens* and specific structures and associated primer sequences required for disrupting the activity; **(B)** regions of the protein/polynucleotide structure which may be modified without affecting the viability of a bryophyte following disrupting any endogenous gene encoding for FucT or XylT in bryophyte cell *Physcomitrella patens*; **(C)** the general tolerance of the polypeptide to modification and extent of such tolerance; **(D)** a rational and predictable scheme for modifying any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and **(E)** sufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claim must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of a transformed bryophyte from *Physcomitrella patens* comprising disruption of any endogenous fucosyl transferase and xylosyl transferase of undefined structure, said bryophyte cell further comprising human beta-1,4-galactosyltransferase capable of producing human glycosylation pattern, is unpredictable and the experimentation left to those skilled in the art is unnecessarily,

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and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

In support of their request that the prior rejection of claims 38-40, 42, 48, 50, 78 and 81-95, under 35 U.S.C. 112, first paragraph for enablement be withdrawn, applicants' provide the following arguments.

All pending claims are directed towards a transformed bryophyte cell from *Pyscomitrella patens*. The specification discusses a variety of bryophytes...(page 15 of response dated 10/21/08).

Reply: These arguments are not found to be non-persuasive for the following reasons.

The key focus of the argument is on the claims as written (see *In re Hinkler* 150 F .3d 1362, 1369, 47 USPQ2d 1523 (fed. Cir. 1998) and not proffered facts and are not commensurate with the scope of claims and therefore unpersuasive. As argued by the examiner above, guidance provided is insufficient, as the breadth and scope of the bryophyte cell *Physcomitrella patens* comprising modifications to a genus of structurally undefined genes (diverse structures for genes associated with fucosyl transferase and xylosyl transferase functions) that are disrupted. Even the applicants in the specification on page 6, lines 10-15 have admitted that N-glycosylation is very complex and well regulated as N-glycosylation depends not only on developmental stages for plants but also dependent upon culture conditions. Therefore a skilled artisan requires the information regarding the gene structure, organization and its regulatory elements of all endogenous genes encoding the polypeptides involved in N-glycan synthesis and

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amenable for disruption without affecting the viability of the modified/transformed plants and the methods for transformation including specific structures such as specific primer sequences for disrupting any FucT or XylT. In addition, any given galactosyltransferase activity (said bryophytes expressing a galactosyltransferase for the production of heterologous glycosylated polypeptides) is specific and limited to certain specific substrate(s) and its spectrum of activity is also limited and specific. In view of the breadth of the claims, the amount of experimentation required, the lack of guidance, working examples, and unpredictability of the art in predicting which of the many bryophytes are amenable for said transformations, practicing the claimed invention would require undue experimentation. As such, the specification fails to enable the entire scope of the claimed invention.

For the above cited reasons examiner is sustaining the argument from the previous Office action dated 04/22/08: As extensively discussed above, neither the specification nor the art provide the structure of all the genes required in the claimed method, or the structural modifications required in all the recited genes such that the desired functional characteristics can be obtained. It is reiterated herein that even if the claims were limited to bryophyte cell *Physcomitrella patens* and the specific modifications disclosed in the specification, that it is unpredictable that the modifications disclosed in the specification would result in similar effects when any endogenous FucT or XylT gene is modified as said *Physcomitrella patens* can potentially comprise multiple distinct genes comprising distinct structures and encoding polypeptides with distinct structures having FucT or XylT activities. As such, one of skill in the art would not

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necessarily conclude that the specific modifications taught in the specification can be applicable to any FucT or XylT gene of said *Pyscomitrella patens*. Furthermore, structure determines function. However, the specification is silent with regard to a structure/function correlation which would allow one of skill in the art to envision all the structures or structural modifications in any FucT or XylT gene of said *Pyscomitrella patens* which would result in the desired functional characteristics. Therefore, for the reasons of record and those set forth above, one cannot reasonably conclude that the full scope of the claimed invention is enabled by the teachings of the specification and/or the prior art.

Maintained-Written Description

Claims 38-40, 42, 48, 50, 78 and 81-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 38-40, 42, 48, 50, 78 and 81-95, as interpreted are directed to a transformed bryophyte from *Pyscomitrella patens* comprising disruption of any endogenous fucosyl transferase and xylosyl transferase of undefined structure, said bryophyte cell further comprising human beta-1,4-galactosyltransferase capable of producing human glycosylation pattern.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject

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matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In the instant case, there are no structural limitations or structure-function correlation recited in claims with regard to: a transformed bryophyte from *Physcomitrella patens* comprising disruption of any endogenous fucosyl transferase and xylosyl transferase of undefined structure. While the specification in the instant application discloses a specific bryophyte *Physcomitrella patens* wherein in said *Physcomitrella patens* the endogenous gene encoding for alpha 1, 3-fucosyltransferase (FucT, 1711 bp, GenBank: partial cDNA: AJ429145, page 32 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 48, 49, 50 and 51 or an endogenous gene encoding for beta 1,2 xylosyltransferase (XylT, 1788 bp, GenBank: corresponding to the coding region: AJ429144, page 38 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 67, 68, 69 and 70 (page 39 of specification) or a double knockout comprising said FucT and XylT disrupted through targeted insertion (double knockout, disrupting the coding regions of said genes, pages 44-45 of specification) further in said single knockout or double knockout *Physcomitrella patens* the gene encoding the human beta-1,4-galactosyltransferase catalyzing the following glycosylation pattern; UDP-galactose + N-acetyl-D-glucosaminylglycopeptide

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⇔ UDP + beta-D-galactosyl 1, 4,-N-acetylbeta-D-glucosaminyglycopeptide (GalT, GenBank X55415) has been integrated by homologous recombination and said *Physcomitrella patens* comprising said gene knockout (FucT and XylT or double knockout) and expressing the human galT is transformed with an expression construct encoding the secretable/soluble form of human vascular endothelial growth factor (VEGF), it fails to provide any information as to a transformed bryophyte from *Pyscomitrella patens* comprising extremely large number of FucT or XylT polynucleotides and encoding polypeptides of undefined structure as broadly encompassed by the claims as said *Pyscomitrella patens* can potentially comprise multiple distinct genes comprising distinct structures and encoding polypeptides with distinct structures having FucT or XylT activities. Due to the lack of description of any additional species/variants/mutants/recombinants of any endogenous FucT or XylT polynucleotides and encoding polypeptides by any identifying characteristics or properties from *Pyscomitrella patens*, one of skill in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In support of their request that the prior rejection of claims 38-40, 42, 48, 50, 78 and 81-95 under 35 U.S.C. 112, first paragraph, for insufficient written description be withdrawn applicants' provide the following argument that are very similar to the arguments provided for traversing the enablement rejection.

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All pending claims are directed towards a transformed bryophyte cell from *Pyscomitrella patens*. The specification discusses a variety of bryophytes...(pages 17-18 of response dated 10/21/08).

Reply: The above arguments are not found to be persuasive for the following reasons.

The broadest interpretation of claims encompasses a transformed bryophyte from *Pyscomitrella patens* comprising extremely large number of FucT or XylT polynucleotides and encoding polypeptides of undefined structure as broadly encompassed by the claims as said *Pyscomitrella patens* can potentially comprise multiple distinct genes comprising distinct structures and encoding polypeptides with distinct structures having FucT or XylT activities and therefore the specification provides only a single species i.e., a specific bryophyte *Physcomitrella patens* wherein in said *Physcomitrella patens* the endogenous gene encoding for alpha 1, 3-fucosyltransferase (FucT, 1711 bp, GenBank: partial cDNA: AJ429145, page 32 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 48, 49, 50 and 51 or an endogenous gene encoding for beta 1,2 xylosyltransferase (XylT, 1788 bp, GenBank: corresponding to the coding region: AJ429144, page 38 of specification) disrupted through targeted insertion by primer sequences SEQ ID NO: 67, 68, 69 and 70 (page 39 of specification) or a double knockout comprising said FucT and XylT disrupted through targeted insertion (double knockout, disrupting the coding regions of said genes, pages 44-45 of specification) of the recited genus, which is insufficient to put one of ordinary

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skill in the art in possession of all attributes and features of all species within the required genus.

The art also teaches, even highly structurally homologous polypeptides do not necessarily share the same function and conversely functionally similar molecules do not necessarily have similar structures. For example proteins having similar structure have different activities; Witkowski et al., (Biochemistry 38:11643-11650, 1999) teaches that one conservative amino acid substitution transforms a β -ketoacyl synthase into a malonyl decarboxylase and completely eliminates β -ketoacyl synthase activity. Similarly, Wishart et al., (J. Biol. Chem., 1995, Vol. 270(10): 26782-26785) teach that a single mutation converts a novel phosphotyrosine binding domain into a dual-specificity phosphatase. The art also teaches that functionally similar molecules have different structures; Kisselev L., (Structure, 2002, Vol. 10: 8-9) teach that polypeptide release factors in prokaryotes and eukaryotes have same function but different structures.

Therefore, the recited genera of polynucleotides and encoding polypeptides are interpreted to have widely variable structures, since minor changes may result in changes affecting function and no additional information correlating structure with function has been provided.

Therefore, given the lack of description of representative species encompassed by the genus of polynucleotides and encoding proteins and modifications, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

- 1) New claim 88 and claims 89-95 depending therefrom are objected to because of informality.
- 2) Claims 38-40, 42, 48, 50, 78 and 81-95 under 35 U.S.C. 112, first paragraph, for enablement and insufficient written description.

Conclusion

Claims 38-40, 42, 48, 50, 78 and 81-95 are objected/rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

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than SIX MONTHS from the date of this final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/
Patent Examiner
Art Unit 1652

/Richard G Hutson/
Primary Examiner, Art Unit 1652